Study Title: Evaluation of Endometriosis With 18F-fluoroestradiol PET / MRI

NCT number NCT04382911
Document Date 03/15/2021

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: March 15, 2021
IRB Study # 20-0328
Title of Study: Evaluation of Endometriosis with 18F-fluoroestradiol PET / MRI
Principal Investigator: Jorge Oldan
Principal Investigator Department: Radiology - Nuclear Medicine
Principal Investigator Phone number: (919) 966-9676
Principal Investigator Email Address: jorge_oldan@med.unc.edu
Study Contact Telephone Number: (919) 843-3670; (919) 843-9463; (919) 966-4997
Study Contact Email: markeela_lipscomb@med.unc.edu; desma_jones@med.unc.edu; terry_hartman@med.unc.edu

---

CONCISE SUMMARY

The purpose of this research study is to test if a new imaging drug, called F-18 Fluoroestradiol (FES), is useful for detecting and diagnosing endometriosis. This investigational drug is used with a PET/MRI scan. We will perform FES-PET imaging to compare results with your laparoscopic surgery results.

You are being asked to take part in this research study because you are scheduled to have a laparoscopy at UNC to determine if you have endometriosis.

If you decide to participate in this research study, you will undergo one (1) scan with the imaging drug, and you will complete questionnaires related to your condition, pain, and quality of life. We will collect information related to your health for up to 3 months after your research scan.

Possible risks associated with FES are swelling and redness at the site of the medication injection, change in taste, and possible allergic reaction. You may experience anxiety and claustrophobia from being in the scanner. You will also be exposed to some radiation from the injection of FES during the study and should not participate if you are pregnant or breastfeeding

With any study, there is a small risk of breach of confidentiality.

There are no direct benefits to you from participating in this study.

If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to evaluate the usefulness of the investigational radiotracer FES with PET/MRI in detecting and diagnosing endometriosis.

You are being asked to take part in this research study because you are scheduled to have a laparoscopy at UNC to determine if you have endometriosis.

Are there any reasons you should not be in this study?

You should not be in this study if you are:

- male
- less than 18 years old
- institutionalized (prisoner or nursing home patient)
- have a known history of breast, ovarian, or endometrial cancer
- pregnant or breast feeding
- unable to have an MRI scan for any reason

How many people will take part in this study?

Approximately 12 people at this institution will take part in this study.

How long will your part in this study last?

Your participation in this study will last a total of 3 months. You will have one study visit and we will review your medical record for up to 3 months following your research scan.

What will happen if you take part in the study?

1. One study visit that will last up to 2.5 hours. This visit will involve:
    - pregnancy test, if applicable
    - questionnaires related to your symptoms, pain, and quality of life. You may choose not to answer a question for any reason.
    - study drug (FES) administration through an IV (needle placed in your arm)
    - one PET/MRI scan

2. One follow-up phone call the day after your study visit to check on you.

3. We will collect study-related health information from your medical records for 3 months following your visit.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

PET/MRI scan

Likely and mild:

- Anxiety/stress
- Claustrophobia
- Discomfort from lying still for imaging (typically about 60 minutes).

IV Needle Placement

Likely and mild:

- Discomfort from the IV and injection of FES into the vein

Infrequent and mild:

- Swelling
- Bleeding
- Infection
- Bruising

Injection of 18F-FES

Infrequent and mild:

- Swelling and redness at the site of medication injection
- Temporary change in taste or smell (i.e a metallic taste or smell) during the injection of FES. Normally goes away within a few minutes of injection.

Rare and Severe:

- Rare possibility of an allergic-type or other adverse reaction to the radioactive labeled tracer FES

A licensed provider will observe you and take your vital signs (blood pressure, pulse) following the administration of FES on through the completion of the imaging. You will also be contacted by study personnel a day after you receive FES to inquire about any delayed onset complications.

Radiation Exposure

Unknown risk and severity:

- Risk of radiation exposure to an unborn child. Women of childbearing age will undergo pregnancy testing prior to FES PET. Pregnant women will be excluded from the study.

Pregnancy tests will be done on all females who might be able to get pregnant at the start of the study. Pregnancy tests are not 100% accurate in detecting very early pregnancy and we strongly advised the use of barrier contraception or to practice abstinence in the timeframe prior to the study procedure.

Pregnancy tests will be paid for by the study.

Risks associated with radiation exposure:
This research study involves exposure to radiation from one FES PET/MRI scan. Please note that this radiation exposure is not necessary for your medical care and is for research purposes only.

The average person in the United States receives a radiation exposure of 0.3 rem (or 300 mrem) per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth's air and soil. The dose that you will receive from participation in this research study is about 0.5 rem, a little more than the amount you receive from these natural sources in 1.7 years.

The amount of radiation you will receive in this study has a minimal risk and is below the dose guideline established by The University of North Carolina Radiation Safety Committee for research subjects. While this level may be considered to have minimal risk for an adult, there are no robust human data to identify a safe level of exposure for an early embryo.

Confidentiality
There is a minimal risk of breach of patient confidentiality. To minimize this risk, you will be given a unique subject ID that will be used for all your data and you will not be identified directly.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What are the risks to a pregnancy or to a nursing child?
We do not know the effect of the study drug on babies before they are born, or on nursing children. Many drugs can get into the mother's milk. You should not breast feed your child while taking the study drug.

If you are a woman and you are planning to get pregnant, you should not be in the study. If you become pregnant during the study you should notify the researcher right away.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

The imaging we are using in this research study is not the same quality as imaging that you may have as part of your health care. The images will not be reviewed by a doctor who normally reads such images (such as a radiologist). As a result, you may not be informed of any unexpected findings. The results will not be placed in your medical record. Occasionally the technologist or principal investigator may notice something abnormal on the imaging. If this

does occur, the images will be reviewed by a qualified doctor to determine if there is anything of clinical importance. If something is found to be important then you, and/or your primary care provider will be notified. Any further follow up and costs associated with the incidental finding will be your responsibility. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate).

Do you wish to be informed in case of clinical/relevant unexpected findings? Please initial in the box below if you do not wish to be notified of clinical/relevant unexpected findings. If you do not initial in the box, you will be notified of any findings.

_____ I do not wish to be notified.

How will information about you be protected?

All of your research records will be stored using a unique ID number only. Research records will be kept in a locked file cabinet within a locked office suite at UNC. Only research team members will have access to individually identifiable data. Research data will be collected using a password protected HIPAA compliant electronic data capture system only accessible by the research team. Extracted research data will be de-identified and coded with a unique ID number. The linkage file will be destroyed at the conclusion of the study and once the final manuscript is published.

Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled

adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal

Will you receive anything for being in this study?
You will be receiving a $175 Visa gift card and parking vouchers for taking part in this study. Any payment provided for participation in this study may be subject to applicable tax withholding obligations.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent